

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kaplan *et. al*

App. No. 10/790885

Art Unit: 3735

Filed: March 1, 2004

Examiner: Gilbert, Samuel G.

DECLARATION OF RICHARD R. BOOTZIN, PhD

Under penalty of perjury of the laws of the State of Arizona, the above named individual declares the following:

1. I am over the age of 18 and competent to provide testimony in this matter.
2. I received a Ph.D. in Psychology from Purdue University in 1968.
3. I am a Professor of Psychology and Psychiatry at the University of Arizona.
4. I am the Director of the University of Arizona Insomnia Clinic.
5. The treatment for insomnia that I introduced in 1972, stimulus control therapy, received the highest standard-of-practice rating from the American Academy of Sleep Medicine in both 1999 and 2006.
6. A true and accurate copy of my *Curriculum Vitae* is attached hereto as Exhibit A.
7. I have reviewed the above named application, Katims (U.S. Patent No. 4,503,863, March 2, 1985) and Wyatt (U.S. Patent No. 6,392,962, May 21, 2002).

8. The above named application teaches a passive tool that allows a patient to monitor his/her sleep status in conjunction with the rules of stimulus control therapy (or other behavior therapies). These rules are outlined in the above named application. *See* page 2 (lines 15-25) and page 3 (lines 1-9); page 14 -page 19 (lines 1-9).

9. Katims teaches a machine that applies an optimal amount of electrical stimulus to a subject who is suffering from neuropsychological disorders in an effort to reduce symptoms. Katims does not teach any type of wake/sleep determination.

10. Stimulus control therapy, as referred to in the above named application, **is not electrical stimulus**, as discussed in Katims. Comparing stimulus control therapy with electrical stimulus, as taught in Katims, is simply incorrect.

11. Wyatt teaches a wrist mounted timer and an actuator in which contacts on a glove worn by the user will be separated at some point before or after the user falls asleep. The purpose of the device is to improve an insomniac's estimation of his total sleep time and efficiency. Such a determination of sleep time and sleep efficiency requires the user to write down when he/she actually lays down, wakes up, and run a calculation in which the time to separation of the contact is used in determining sleep efficiency.

12. Wyatt cannot indicate when the user falls asleep because the loss of motor control associated with the separation of the contacts is not a reliable indicator of the time that the user fell asleep. The probable inconsistency between the time to fall


asleep and the actually sensed time to fall asleep could upset an already concerned user leading to further bad sleep hygiene and continuing insomnia.

13. Even assuming that Wyatt could be considered an active means of determining wake/sleep, Wyatt does not teach a passive wake/sleep determination as taught in the above named application.


14. Wyatt does not teach drug therapy and specifically teaches away from the use of drug therapy. (Column 3, lines 1-18).

15. Neither Katims nor Wyatt discusses any motivation to lead a person of ordinary skill in the medical arts to combine the teachings of Katims with Wyatt.

16. At the time the invention was made, a person of ordinary skill in the medical arts would have no reason to combine the teaching of Katims with Wyatt. Assuming that Wyatt teaches an active wake/sleep determination, before the current application was made, in March 2004, a person of ordinary skill in the medical arts would not have any motivation to combine electrical stimulus with an active wake/sleep determination. Further, a person of ordinary skill in the medical arts would not have any motivation to combine electrical stimulus with an active sleep/wake determination, and drug therapy.



Richard R. Bootzin, PhD



Date